REMARKS

Claims 1-4, 17-25, 27-32 were presented for examination and were rejected.

The applicants have amended claim 1, support for which can be found in former claims 4, 24 and 27, and also on page 7, line 14 of the published PCT application.

Other claims have been amended to maintain proper antecedent basis and claim dependency.

Claims 4, 24, 27, 31, and 32 were canceled without prejudice, and the applicants respectfully reserve the right to re-present any or all of these claims in this or another application.

The applicants respectfully request reconsideration in light of the amendments and the following comments.

Applicants' Remarks in Regard to "Response to Amendment" Section

The Examiner has declined to take the Declaration under 37 CFR 1.132, previously filed on this case, into account. This is on the ground that it is allegedly "difficult to distinguish to what extent the difference in elution is due to the spiral configuration or the aspirin load in order to determine if the results were entirely unexpected."

The Declaration contained data which demonstrated that the elution of aspirin from a stent containing a spiral formation was greater than from a control stent. The Examiner's position is that this may have been due to the increased load of aspirin on the spiral stent which would render the results "obvious" (as stated in section 1 of the Office action mailed on March 17, 2009). It should be noted, however, that even if the improved results are due to the increased aspirin load on the spiral stent, there is no teaching in the cited art that would render it obvious that a stent with a spiral formation would be able to carry a greater load of aspirin than a stent without a spiral formation. For this reason, the applicants respectfully submit that the Examiner is incorrect to assert that this result is "obvious."

35 U.S.C. § 103 Rejection of Claims 1, 3, 4, 20-21, 24, 25 and 32

Claims 1, 3, 4, 20-21, 24, 25 and 32 were rejected under 35 U.S.C. § 103 as being unpatentable over Brown et al, U.S. Patent 6,071,305 (hereinafter "Brown") in view of

Greenhalgh, U.S. Patent 6,159,239 (hereinafter "Greenhalgh"). The applicants respectfully submit that the amendment to the claims overcome the rejection.

Claim 1, as amended, recites:

> **1.** A drug delivery device comprising: a drug; *a wire mesh intravascular stent* having a blood-contacting surface; and a stent insert comprising a helical formation, made from a polymer, on the blood contacting surface, *the helical formation comprising at least one fin* and having a helix angle of between 8° and 20° and being capable of inducing helical flow of blood flowing past the helical formation, and the drug being releasably associated with the helical formation of the stent insert.
>
> (*emphasis added*)

Neither Brown nor Greenhalgh teaches, suggests or motivates, alone or in combination with each other, what amended claim 1 recites—namely, a drug delivery device comprising a wire mesh intravascular stent, with a helical formation comprising at least one fin and with which the drug is releasably associated.

As an initial point, note that Brown does not disclose the provision of a "mesh intravascular stent." The Examiner refers to the drug delivery stent 11 in Brown as corresponding to the intravascular implant of claim 1. However, it is clear from Figures 1 and 2 of Brown that the stent 11 does not comprise a mesh; it is only a solid helical component.

The Examiner suggests that it would have been obvious for a skilled person to combine the teachings of Brown and Greenhalgh in order to arrive at a drug delivery device in accordance with claim 1. However, even if a skilled person combined the teachings of Brown and Greenhalgh, he would still not arrive at the drug delivery device as defined in claim 1. Greenhalgh does not disclose the provision of a wire mesh intravascular stent. In Greenhalgh, it is stated that the main body of the drug delivery device is a "textile graft 12" (see column 5, line 52 of Greenhalgh). There is no disclosure of a wire mesh stent.

Furthermore, the Examiner has suggested that Greenhalgh teaches the provision of a helical formation having a helix angle between 10° and 85°. In this regard, the Examiner refers to Figure 12 and column 13, line 57 to column 14, line 10 of Greenhalgh. In particular, the Examiner refers to the helical stent 72 in Greenhalgh. However, it is to be appreciated that the stent member 72 of Greenhalgh is not a counterpart of the drug delivery stent 11 of Brown. As can be seen in Figures 4A and 4B of Greenhalgh, the "first stent member" (which in Figures 4A and 4B is item 26) does not extend from the surface of the textile graft 12; instead, it is embedded within it. In this position the stent member could not influence the flow of blood. Furthermore, it is clear from Figures 4A and 4B that

the stent member 26 does not comprise "at least one fin." Instead the stent member 26 in Greenhalgh is of a circular cross-section. Therefore, even if a skilled person were to combine the teachings of Greenhalgh and Brown, then he would not produce a drug delivery device which had a helical formation that comprised at least one fin and that was "capable of inducing helical flow of blood flowing passed the helical formation."

To summarize, if a skilled person were to combine the teachings of Brown and Greenhalgh, he would not arrive at a drug delivery device comprising a wire mesh intravascular stent since this feature is disclosed in neither document. Furthermore, the helical formation of the combined product would not comprise at least one fin, as Greenhalgh requires that the stent member is "wire-shaped" (see column 6, line 8 of Greenhalgh). For these reasons, the applicants respectfully submit that the rejection of claim 1 is overcome.

Because claims 3, 20-21, and 25 depend on claim 1, the applicants respectfully submit that the rejection of them is also overcome. Note that claims 4, 24, and 32 have been canceled.

35 U.S.C. 103 Rejection of Claim 2

Claim 2 has been rejected under 35 U.S.C. 103 as being unpatentable over Brown in view of Greenhalgh, as applied to claim 1 above, and further in view of Kaplan, U.S. Patent 5,342,348 (hereinafter "Kaplan").

Because claim 2 is dependent upon claim 1 and because Kaplan fails to cure the deficiencies of Brown and Greenhalgh with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claim 2 is overcome as well.

35 U.S.C. 103 Rejection of Claims 17 and 18

Claims 17 and 18 have been rejected under 35 U.S.C. 103 as being unpatentable over Brown in view of Greenhalgh,as applied to claim 4 above, and further in view of Dutta et al, U.S. Patent 6,702,849 (hereinafter "Dutta").

The subject matter of claim 4 has been incorporated into claim 1. Because claims 17 and 18 are dependent upon claim 1 and because Dutta fails to cure the deficiencies of Brown and Greenhalgh with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claims 17 and 18 is overcome as well.

35 U.S.C. 103 Rejection of Claim 19

Claim 19 has been rejected under 35 U.S.C. 103 as being unpatentable over Brown in view of Greenhalgh as applied to claim 4 above, and further in view of Davila et al, U.S. Patent Publication No. 2002/0111590A1 (hereinafter "Davila").

The subject matter of claim 4 has been incorporated into claim 1. Because claim 19 is dependent upon claim 1 and because Davila fails to cure the deficiencies of Brown and Dutta with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claim 19 is overcome as well.

35 U.S.C. 103 Rejection of Claims 22 and 23

Claims 22 and 23 been rejected under 35 U.S.C. 103 as being unpatentable over Brown in view of Greenhalgh, as applied to claim 21 above, and further in view of Banas et al, U.S. Patent 5,749,880 (hereinafter "Banas").

Because claims 22 and 23 are dependent upon claim 1 and because Banas fails to cure the deficiencies of Brown with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claim 22 and 23 is overcome as well.

35 U.S.C. 103 Rejection of Claims 27-31

Claims 27-31 have been rejected under 35 U.S.C. 103 as being unpatentable over Brown in view of Greenhalgh, as applied to claim 1 above, and further in view of Stinson, U.S. Patent Publication No. 2004/0044397A1 (hereinafter "Stinson").

Because claims 27-31 are dependent upon claim 1 and because Stinson fails to cure the deficiencies of Brown with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claims 27-31 is overcome as well.

35 U.S.C. § 103 Rejection of Claims 1-4, 17-25, and 27-32

Claims 1-4, 17-25, and 27-32 were rejected under 35 U.S.C. § 103 as being unpatentable over Houston et al, U.S. Patent Publication No. 2003/0139807 (hereinafter "Houston") in view of Falotico et al, U.S. Patent 7,195,640 (hereinafter "Falotico") in view of Greenhalgh. The applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 1, as amended, recites:

> **1.** A drug delivery device comprising: a drug; a wire mesh intravascular stent having a blood-contacting surface; and a stent insert comprising a helical formation, made from a polymer, on the blood contacting surface, the helical formation comprising at least one fin and *having a helix angle of between 8° and 20°* and being capable of inducing helical flow of blood flowing past the helical formation, and the drug being releasably associated with the helical formation of the stent insert.
>
> (*emphasis added*)

The Examiner asserts that Houston discloses all of the features the drug delivery device of claim 1 except for the provision of a drug and the helix angle of the helical formation being between 8° and 20°. However, even if a skilled person were to combine the teachings of these three documents, then he would not arrive at a drug delivery device in accordance with claim 1.

More specifically, the Examiner argues that Greenhalgh teaches a helical stent 72 having a helix angle between 10° and 85°, and that therefore the skilled person would adapt the teachings of Houston to produce a helical formation having a helix angle within this range. However, the stent member 72 of Greenhalgh is not a direct counterpart to the insert 2 of Houston. As explained above, the stent member 72 of Greenhalgh is woven within the textile graft 12 of Greenhalgh. In contrast, in Houston the insert is not woven into the conduit 4. On the contrary, the insert sits within the conduit 4 of Houston. For example, referring to Figure 2 of Houston it is clear that there is no weaving of the insert 2 into the conduit 4.

Furthermore, the role of the stent member 72 in Greenhalgh is completely different from the role of the insert 2 in Houston. Although it is never clearly stated in Greenhalgh, it is implied that the purpose of the stent member is that it can undergo substantially elastic deformation in expanding from a first position to a second position, by virtue of the energy stored within it (see column 9, lines 11 to 17 of Greenhalgh). In contrast, the purpose of the insert 2 in Houston is to generate spinal flow in blood (see paragraph [0040] of Houston).

Therefore, even if a skilled person were to combine the teachings of Greenhalgh and Houston, it is not obvious that he would adjust the helix angle of the insert of Houston into the range identified in Greenhalgh. On the contrary, since the purpose of the stent member in Greenhalgh is different from the insert in Houston and since the stent member in Greenhalgh is woven into the textile graft 12, which would defeat the object of the insert 2 in Houston, the obvious combination of the two documents would actually be to supplement

the conduit of Houston with the stent member from Greenhalgh. However, such a combination would not result in a helical formation comprising at least one fin and having the helix angle recited in claim 1 since the stent member of Greenhalgh does not comprise at least one fin.

For these reasons, the present invention as defined in claim 1 would not be an obvious combination of the cited references, and the applicants respectfully submit that the rejection of claim 1 is overcome.

Because claims 2-3, 17-23, 25, and 27-30 depend on claim 1, the applicants respectfully submit that the rejection of them is also overcome. Note that claims 4, 24, 31, and 32 have been canceled.

Request for Reconsideration Pursuant to 37 C.F.R. 1.111

Having responded to each and every ground for objection and rejection in the last Office action, applicants respectfully request reconsideration of the instant application pursuant to 37 CFR 1.111 and request that the Examiner allow all of the pending claims and pass the application to issue.

If there are remaining issues, the applicants respectfully request that Examiner telephone the applicants' agent so that those issues can be resolved as quickly as possible.

Respectfully,
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